REMARKS/ARGUMENTS

1. Claim Amendments

Claim 8 has been amended to recite a pharmacological composition "for the treatment of carcinoma." The amendment is supported in the specification, for example, in paragraphs [0011], [0048], and example 1 paragraph [0050] which all recite the use of LCAM1 in the treatment of various carcinomas including breast and cervical. No new matter has been added as a result of this amendment.

2. Objections-Specification Amendments

The Abstract of Disclosure is objected to for including "legal phraseology often used in patent claims, such as 'means' and '_said_'." The Abstract has been amended to no longer recite "said." No new matter has been added as a result of these amendments.

3. Claim Rejections 35 USC §102

a. Claims 8 and 9 are rejected under 35 US § 102 (b) as being anticipated in view of Hoefnagel et al. The Applicants traverse this rejection.

According to M.P.E.P. §2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." _Verdegaal Bros. v. Union Oil Co. of California_, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As discussed above, Claim 8 has been amended to recite that the claimed pharmaceutical composition is "for the treatment of carcinoma." As noted by the Action, "Hoefnagel discloses the therapeutic efficacy of ^{131}I-labeled chCE7 (chimeric murine anti-human L1CAM mAb) in nude mice bearing neuroblastoma xenografts." Hoefnagel et al. also showed that the chCE7 antibody can recognize neuroblastoma and renal carcinoma cells. However, Hoefnagel et al. do not teach or suggest the use of an anti-L1CAM antibody or L1CAM-binding fragment have any effect on growth of carcinoma cells, and thus do not teach or suggest that L1CAM antibodies are useful for the treatment of carcinoma. Consequently,

Hoefnagel et al. cannot anticipate claim 8 or its dependent claim 9. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

b. Claims 8 and 9 are rejected under 35 US § 102 (b) as being anticipated in view of Carrel et al. The Applicants traverse this rejection.

Carrel et al. teach the use of an L1CAM-binding fragment for targeting neuroblastoma tumor cells. As discussed above, Claim 8 has been amended to recite that the claimed pharmaceutical composition is "for the treatment of carcinoma." Carrel et al. do not teach or suggest the use of an anti-L1CAM antibody or L1CAM-binding fragment can be used to treat carcinoma, and thus Carrel et al. do not render claim 8 or its dependent claim 9 anticipated. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

c. Claims 8 and 9 are rejected under 35 US § 102 (b) as being anticipated in view of Mujoo et al. as evidenced by Wolff et al.

Mujoo et al. teach an L1CAM antibody that recognizes and can target neuroblastoma cells to demonstrate the usefulness of conjugating L1CAM antibodies to drugs or radionucleotides for treating neuroblastoma. Mujoo et al. do not teach that L1CAM antibodies or fragments thereof can be used to treat carcinomas. On the contrary, the L1CAM antibodies taught by Mujoo et al. were unable to recognize carcinoma cells (see Table II on page 10302). Wolff et al., as pointed out by the Action, merely discloses that the Mujoo et al. antibody can bind human and murine L1 antigens. Since neither one of these references teaches or suggests that an anti-L1CAM antibody or L1CAM-binding fragment can be used to treat carcinomas, these references cannot anticipate claims 8 and 9, because as discussed above, claim 8 has been amended to recite that the claimed pharmaceutical composition is "for the treatment of carcinoma." Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

d. Claims 8 and 9 are rejected under 35 US § 102 (b) as being anticipated in view of Patel et al. The Applicants traverse this rejection.

The Action points out that Patel et al. teaches L1CAM antibodies that bind to human L1 antigen on neuroblastoma lines and rhabdomyosarcoma cell line JR1, and suggest the use

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of the antibodies for studying the molecular biology of L1 (see page 489). Patel et al. do not teach or suggest the use of an anti-L1CAM antibody or L1CAM-binding fragment for the treatment of carcinoma. Since, claim 8 and 9 encompass compositions for the treatment of carcinoma, Patel et al. cannot anticipate the instant claims. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

4. Claim Rejections 35 USC §103

a. Claim 8 is rejected under 35 USC 103(a) as being obvious over Rathjen et al, in view of Cleland et al. The Applicants traverse this rejection.

In order to establish a *prima facie* case of obviousness the Patent office must establish three criteria; 1) a suggestion or motivation found within the prior art or within the knowledge of one of skill in the art to combine or modify the references; 2) a reasonable expectation of success; and 3) the prior art references alone or in combination must teach or suggest *all* the claim limitations. MPEP § 706.02(j).

The combination of Rathjen et al. and Cleland et al. does not teach or suggest at least the following limitations of amended claim 8:

"…a pharmaceutical composition **for the treatment of carcinoma**."

Rathjen et al. teach L1 polyclonal and monoclonal antibodies that can react with neuroblastoma cells, and L1 polyclonal antibody fragments that can inhibit aggregation of neuroblastoma cells. Rathjen et al. do not teach, suggest, or make obvious to those of skill in the art the use of an anti-L1CAM antibody or L1CAM-binding fragment for the treatment of carcinoma. Cleland et al. do not cure this deficiency. Specifically, Cleland et al. merely teach excipients for stabilizing a monoclonal HER2 antibody. Cleland et al. do not teach use of an anti-L1CAM antibody or L1CAM-binding fragment for the treatment of carcinoma. Consequently, Applicants respectfully submit that the combination of Rathjen et al. and Cleland et al. do not render the instant claim obvious, because the cited references do not teach or suggest pharmaceutical compositions for the treatment of carcinoma. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

b. Claims 8 and 9 are rejected under 35 USC 103(a) as being obvious over Wolff et al, in view of Cleland et al. The Applicants traverse this rejection.

Wolff et al. teach "the potential involvement of 5G3 or L1 in various human neurological disorders." Wolff et al. do not teach, suggest, or make obvious to those of skill in the art the use of an anti-L1CAM antibody or L1CAM-binding fragment for the treatment of carcinoma. Cleland et al., as discussed above, does not teach or suggest the use of L1CAM antibody or L1CAM-binding antibody fragments for the treatment of carcinoma. Thus, Applicants respectfully submit that these references do not render the instant claims obvious. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.
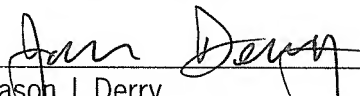
CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If the Examiner believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,

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